



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53311

October 14, 1997

Alfred C. Bairos
DeSimas and Bairos Dairy
4137 Oakdale-Waterford Highway
Oakdale, California 95361

WARNING LETTER

Dear Mr. Bairos:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on September 16, 1997, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On July 11, 1997, you consigned a calf (identified by USDA laboratory report number 384736) for slaughter as human food. This calf was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this animal revealed the presence of sulfadimethoxine in the liver at a level of 27.0 parts per million (ppm) and in the muscle at a level of 21.0 ppm. A tolerance level for sulfadimethoxine has been established at 0.1 ppm for the edible tissues of cattle.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions ...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.
2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.
4. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
5. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

You are adulterating the drug SmithKline Beecham brand of Albion Soluble Powder containing sulfadimethoxine within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v), and it is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Labeling warns against releasing animals for slaughter for food within seven days of use. Failure to adhere to the recommended withdrawal time is likely the cause of the illegal antibiotic residues in the calf you sold at auction. Failure to adhere to labeling directions for a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

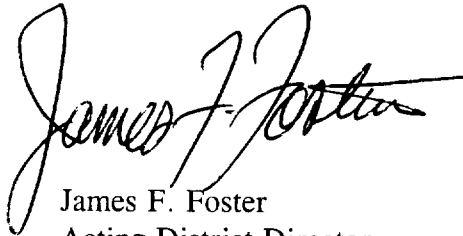
DeSimas & Bairos Dairy
Oakdale, California

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You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to an auction yard where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Within fifteen (15) days of the receipt of this letter, notify our Fresno resident post office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to John A. Gonzalez, Investigator, United States Food and Drug Administration, 2202 Monterey Street, Suite 104 E, Fresno, California 93721.

Sincerely yours,

A handwritten signature in black ink, appearing to read "James F. Foster". The signature is fluid and cursive, with a large initial "J" and "F".

James F. Foster
Acting District Director
San Francisco District

cc:

A large rectangular area of text has been completely blacked out (redacted) with heavy marker.A second large rectangular area of text has been completely blacked out (redacted) with heavy marker.